

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: DIGITEK<sup>®</sup> PRODUCT LIABILITY  
LITIGATION

MDL NO. 1968

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THIS DOCUMENT RELATES TO ALL CASES

**REPLY MEMORANDUM IN SUPPORT OF**  
**DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

In their Response, Plaintiffs promise “ample evidence that defective, excess-strength Digitek reached the marketplace and were consumed by Plaintiffs.” (Doc. 549 at 1). They do not deliver. Instead, they dwell on Actavis’s regulatory history and a series of past alleged “production deficiencies” that have nothing to do with whether any plaintiff received an out-of-specification Digitek<sup>®</sup> tablet. That so-called evidence is the product of Plaintiffs’ efforts to spin the record by mischaracterizing documents (including their own experts’ reports) and by attaching a “sham affidavit” from Dr. David Bliesner.

Now, as though they belatedly recognize the flimsy nature of their proof, Plaintiffs take the unprecedented step of asking this Court to forgive their lack of evidence by flipping the burden of proof onto Defendants. There is no support for giving any such escape valve to a plaintiff in a manufacturing defect case like this one. Plaintiffs have had more than three years to develop a record and refine their theories; now they must finally identify where that record contains any evidence that out-of-specification Digitek<sup>®</sup> tablets reached each plaintiff. That they *admittedly* cannot do so confirms the absence of any “genuine dispute as to any material fact” and, accordingly, calls for this Court to end this protracted litigation.

**A. There Is No Support for Plaintiffs' Burden-Shifting Argument.**

Although Plaintiffs bury their burden-shifting request 14 pages into their Response, Defendants address this unprecedented argument first in order to frame the subsequent discussion regarding Plaintiffs' inadequate proof. At the outset, Plaintiffs' argument is essentially an admission that Plaintiffs cannot meet their burden of proving that any out-of-specification tablets reached the market. (*See* Doc. 549 at 15-16). Their request lacks any authoritative support. The *only* case they cite, *Haft v. Lone Palm Hotel*, 3 Cal.3d 756, 774 n.19 (Cal. 1970),<sup>1</sup> applies to a narrow set of circumstances not at issue in this litigation.

*Haft* has no applicability where, as here, a plaintiff's task is to prove defect. Its burden-shifting rule applies only "where there is a substantial probability that a defendant's negligence was a cause of an accident, and when the defendant's negligence makes it impossible, as a practical matter, for plaintiff to prove 'proximate causation' conclusively." *Id.* (emphasis added). That the rule on its face applies only to "causation" confirms that Plaintiffs cannot shift the burden as to liability issues like proof of defect.<sup>2</sup> Here, Plaintiffs must first prove that there *were* defective Digitek® tablets before they can claim "we ate all the defective ones."

Additionally, Plaintiffs cannot abdicate their burden of proof under *Haft* when, in the more than three years since the Digitek® recall, they scarcely attempted to determine whether they possess out-of-specification Digitek®. Plaintiffs cannot credibly call it "impossible" to acquire direct evidence when (as Defendants explained in their Memorandum in Support of Summary Judgment, Doc. 524 at 8 n.6) some possess but refuse to test (or reveal any testing of)

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<sup>1</sup> For some reason, Plaintiffs chose to file the same brief opposing summary judgment in all MDL cases as the Plaintiff in the McCornack case, notwithstanding that the substantive law the McCornack Plaintiff cites (California authority) does not apply to any other case in MDL 1968.

<sup>2</sup> Plaintiffs characterize their argument in a subheading as applying to the burden of proving causation (*see* Doc. 549 at 15), but their argument, which addresses whether "Plaintiffs should have been able to locate a defective tablet," clearly pertains to proving defect, (*see id.*).

unused Digitek<sup>®</sup> tablets. As this Court observed in denying Plaintiff's Motion to Set Trial Date and Amend Scheduling Order (McCornack Doc. 79) in the McCornack case:

The plaintiffs have had 97 or more of Mr. McCornack's very own unused Digitek tablets in their possession since the day this case was filed. . . . Counsel could have tested those readily available pills long ago and compared the results to the ANDA information.

(McCornack Doc. 116 at 6-7).<sup>3</sup> Yet instead of measuring or testing tablets to determine whether they have any direct evidence of defective Digitek<sup>®</sup>—as this Court suggested—Plaintiffs dismiss the search for an out-of-specification tablet as futile, like searching for “a needle in a 10,000 acre hayfield.” (Doc. 549 at 16).

The analogous case is not *Haft*, but *Dick v. American Home Products Corp.*, which Defendants previously detailed. (See Doc. 524 at 15). In *Dick*, the plaintiffs alleged that Wyeth-produced etodolac capsules were defective because they contained errant amounts of a chemical called acebutolol. No. 1:05-cv-2384, 2009 WL 1542773 (M.D. Penn. June 2, 2009). The *Dick* plaintiff also lacked direct evidence. But when the plaintiff failed to produce evidence “that any etodolac capsules Mr. Dick did ingest . . . actually contained any acebutolol,” the court did not shift the burden of proof. *Id.* at \*3. Rather, it held the plaintiff to his burden—whether he consumed his only out-of-specification tablet or not—and granted summary judgment because plaintiff could not prove defect. *Id.* Here too, Plaintiffs' failure to carry their burden of proof calls for summary judgment.

**B. Plaintiffs' Evidence Does Not Raise a Genuine Issue of Material Fact as to Whether Defective Digitek<sup>®</sup> Reached the Market, Much Less Any Plaintiff.**

To preclude summary judgment, Plaintiffs must show evidence that Digitek<sup>®</sup> tablets released to the market did not meet their FDA-approved specifications. There is no such

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<sup>3</sup> Likewise, the Vega Plaintiff has one leftover tablet that has not been measured or tested.

evidence in the record. Undeterred, Plaintiffs now editorialize on—and ultimately, mischaracterize—the record by drawing unsupported conclusions that documents, including their own experts’ reports, indicate the presence of out-of-specification Digitek® in the marketplace when they do not. Their legally and factually incorrect arguments do not create a genuine dispute as to whether defective Digitek® reached the market.

**1. Plaintiffs ignore the difference between an “adulterated” and “defective” drug.**

Plaintiffs’ Response completely ignores and does not contest Defendants’ explanation that, as a matter of law, “adulteration” does not mean “defect.” Even Plaintiffs’ experts admitted this. (*See* Mem. in Support of Defs’ Mot. to Exclude, Doc. 526 at 3). Instead, Plaintiffs make adulteration the lynchpin of their case, notwithstanding that evidence of adulterated Digitek® is not evidence that there was anything substantively *wrong* with Digitek® or that out-of-specification tablets reached consumers. (*See* Doc. 524 at 8-11).

If a plaintiff wants to rely on evidence referring to a cGMP violation as proof of defect, that plaintiff must “drill down” into the otherwise irrelevant documentation of the alleged violation to determine whether it addresses facts that actually pertain to the drug’s content or specifications. These Plaintiffs have not done so. Worse, on several occasions they affirmatively represent that these violations *do* relate to out-of-specification tablets when they do not. The following section dispels some of the most egregiously misleading examples.

**2. Plaintiffs mischaracterize the record to fabricate evidence that out-of-specification Digitek® tablets reached the marketplace.**

Undeterred by the difference between adulteration and defect, Plaintiffs cite a series of documents allegedly related to “a decades-long history of serious production deficiencies” and ask this Court to accept that history as proof that out-of-specification Digitek® reached the market. But these documents say nothing about the presence of out-of-specification Digitek® in

the marketplace. In fact, some say nothing about any drug “production” process at all. And in most cases, it appears that Plaintiffs have done no more than copied and pasted portions of Dr. Bliesner’s expert report and revised his language to suggest that the documents discussed out-of-specification Digitek®. This approach openly mischaracterizes the evidence. For example:

- On page 3, Plaintiffs cite an FDA form 483 reporting “‘thin’ (*i.e.*, sub-strength) tablets . . . during a visual inspection.” (*See* Pls’ Exhibit 236). These tablets were not Digitek®. The tablets were “round, green colored tablets,” but Digitek® is either yellow or white. (*Compare id.* at 4 with Pls’ Exhibit 516 at 3).
- On page 3, Plaintiffs cite the June 8, 2004 discovery of a double-thick/double-weight 0.25 mg digoxin tablet. This tablet, produced in November 2003, was not from a recalled batch. In fact, additional procedures and safeguards were implemented between the time of this incident and the 2008 recall, and the FDA itself confirmed that this “was considered an isolated incident.” (*See* Pls’ Exhibit 128 at 4; Defs’ Exhibit 71 at 6; Doc. 522 at 20)
- On page 4, Plaintiffs claim that in January 2008, Mylan “confirm[ed] two batches of 0.125 mg Digitek with out-of-specification assays (too low).” But the assays for these two batches were *not* out of specification. While “low” by Mylan’s internal standards, these batches (70926A1 and 70953A1) fell within the FDA-approved range of 90.0% to 105.0%. (*See* Pls’ Exhibit 016 at 46).
- On page 4, Plaintiffs state that UDL noted “the complaint of a consumer who received sub-thickness tablets” in March 2008. This is a customer complaint that has never been verified by any scientific measurement or testing process. Indeed, the tablet at issue may never have been measured by anyone. For that matter, UDL concluded there was “no evidence of unusual events that could be related to the packaging of double the thickness tablets in unit dose blisters.” (Pls’ Exhibit M69 at 5).
- On page 4, Plaintiffs report that “a Digitek tablet ‘obviously of double thickness’” was discovered in late April 2008 “at a Massachusetts nursing facility.” Defendants have already explained the reasons why this post-recall evidence should be excluded in their Motion to Exclude Unreliable Hearsay. (Doc. 527).
- On page 4, Plaintiffs refer to nine consumer complaints “of double-thick Digitek found in the marketplace” received in January 2009. These post-recall complaints, after the MDL was established, are also unverified consumer complaints and the tablets were never scientifically measured or tested to confirm whether they met specifications.
- And throughout pages 3 and 4, Plaintiffs refer to batches of Digitek with alleged “blend uniformity failures,” none of which can serve as the basis for an inference of product defect for the reasons articulated in Defendants’ General Background Statement of Key Factual Information Regarding Digitek. (Doc. 522 at 18-20).

In short, of the 20 pieces of circumstantial evidence that Plaintiffs cite in their response (Doc. 549 at 3-5), only four have *any* plausible connection to out-of-specification Digitek® in the market. One was identified in 2004—years before the recall that precipitated this litigation. Another was an unconfirmed report filtered through at least one, and possibly multiple layers of hearsay, that is the subject of one of Defendants’ evidentiary motions. And the remaining two are unsubstantiated consumer reports, which have never been validated, regarding tablets that have never been measured, or tested.<sup>4</sup> In short, none of this amounts to admissible evidence that Actavis produced out-of-specification Digitek® tablets that reached the market, much less any of the plaintiffs in this litigation. Plaintiffs cannot prove the narrow proof-of-defect issue in this case by referring to a broadly irrelevant, company-wide, and decades-long history of “production deficiencies.”<sup>5</sup>

**3. Plaintiffs may not use inferences drawn from one plaintiff’s lengthy medical history to prove defect.**

Amid a lengthy discussion of Daniel McCornack’s medical history—a discussion relevant only to Case No. 2:09-cv-00671<sup>6</sup>—Plaintiffs state that they can prove their prima facie case with “circumstantial evidence of a malfunction of a product.” (Doc. 549 at 19-20).

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<sup>4</sup> In fact, it is this very reason why adverse event reports (“AERs”) are routinely barred from evidence. *See, e.g., McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) (holding that AERs, as “[u]ncontrolled anecdotal information,” offer “one of the least reliable sources to justify opinions about both general and individual causation.”); *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002) (adverse event reports “reflect only reported data, not scientific methodology” and “cannot be tested”). Plaintiffs withdrew their only expert on AERs, Karen Frank, and now lack any expert who can reliably draw any conclusions from these sorts of complaints.

<sup>5</sup> Indeed, this Court has recognized that evidence of production deficiencies related to Actavis products other than Digitek is of attenuated relevance, if any. In Pretrial Order 27, denying Plaintiffs’ Motion to Expand Scope of Discovery, Judge Stanley rejected Plaintiffs’ argument that “an incident involving one product ‘would be similar or even identical’ to an incident involving Digitek®,” as “too speculative to justify the enormous and expensive expansion of discovery they seek.” (Doc. 150 at 15). Given the broad scope of discovery allowed under the Federal Rules of Civil Procedure, Judge Stanley’s observation underscores the very substantial relevance problems posed by any evidence unrelated to the Digitek® manufacturing process. *See* Fed. R. Civ. P. 26(b)(1).

<sup>6</sup> Defendants address Mr. McCornack’s medical history in their reply brief filed in the *McCornack* case.

Specifically, they propose that the fact (if proven) that a plaintiff experienced digoxin toxicity could prove that the plaintiff received defective Digitek<sup>®</sup>. (*See id.*). Their argument is factually and legally incorrect, as explained in Defendants' Memorandum in Support of Summary Judgment, because digoxin toxicity occurs naturally at even therapeutic dosages, and so is not indicative of whether Digitek<sup>®</sup> met its FDA-approved specifications. (*See* Doc. 524 at 16-17).

The malfunction theory, on which Plaintiffs depend, should be applied only where the inference between malfunction and defect is straightforward and reliable. For example, an inference of defect may arise when a new tire explodes under ordinary use. But a prescription drug is not like a tire because there may be many explanations apart from defect as to why the drug "malfunctioned." (*See* Doc. 524 at 6-7). The non-binding California cases cited by Plaintiffs in support of their argument involve products much more akin to a tire—for which there are few explanations for a malfunction—than to a drug. *See Hinckley v. La Mesa R.V. Center, Inc.*, 158 Cal. App.3d 630 (Cal. Ct. App. 1984) (motor home burned after engine caught fire); *Notmeyer v. Stryker Corp.*, 502 F. Supp.2d 1051 (N.D. Cal. 2007) (prosthetic hip device shattered). The malfunction theory may have been appropriate in those cases, but not here.

**C. This Court Should Disregard Dr. Bliesner's August 24, 2011 Declaration Under Rule 26 and as a "Sham Affidavit."**

Dr. David Bliesner—whose report contained *no* references to "defective" or "out-of-specification" Digitek<sup>®</sup>—offers a new and contradictory set of opinions in his declaration attached to Plaintiffs' Response. (*Compare* Bliesner Report with Pls' Exhibit 620). This Court should disregard his declaration and exclude these new opinions from evidence for two reasons, one rooted in Rule 26 and one based on the "sham affidavit" rule.

First, Dr. Bliesner's declaration is an improper attempt to supplement his expert opinions under Rule 26(e)(2). While supplementation may be used "to correct inadvertent errors or

omissions,” it is *not* a “license to amend an expert report to avoid summary judgment.” *Gallagher v. S. Source Packaging, LLC*, 568 F. Supp. 2d. 624, 630 (E.D.N.C. 2008). It is particularly appropriate to bar an expert’s submission when the expert’s new opinions are tailored responses to the arguments offered in the movant’s motion for summary judgment:

It would appear that Nuschke’s much expanded opinion was prompted solely by ArvinMeritor’s summary judgment motion. Indeed, as ArvinMeritor points out, much of Nuschke’s Declaration reads like a legal brief in that Nuschke often describes ArvinMeritor’s summary judgment arguments then responds to them. This is not the proper role for supplementation of a report by an expert.

*Solaia Tech., LLC v. ArvinMeritor, Inc.*, 361 F. Supp. 2d 797, 806 (N.D. Ill. 2005).

Dr. Bliesner’s declaration—much like the expert opinions described in *ArvinMeritor*—reads like a brief opposing Defendants’ Motion for Summary Judgment. To allow an expert like Dr. Bliesner to add never-before-expressed opinions about out-of-specification and defective Digitek® would embrace a limitless and unprecedented interpretation of Rule 26(e)(2). *See Akeva L.L.C. v. Mizuno Corp.*, 212 F.R.D. 306, 310 (M.D.N.C. 2002) (“To construe supplementation to apply whenever a party wants to bolster or submit additional expert opinions would [wreak] havoc [on] docket control and amount to unlimited expert opinion preparation.”).

Second, the Fourth Circuit holds that plaintiffs cannot avoid summary judgment by simply attaching a declaration that contradicts a witness’s prior testimony. *See, e.g., Barwick v. Celotex Corp.*, 736 F.2d 946, 960 (4th Cir. 1984); *Rohrbough v. Wyeth Labs., Inc.*, 916 F.2d 970, 975 (4th Cir. 1990). The reason for this rule is straightforward: “If a party who has been examined at length on deposition could raise an issue of fact simply by submitting an affidavit contradicting his own prior testimony, this would greatly diminish the utility of summary judgment as a procedure for screening out sham issues of fact.” *Barwick*, 736 F.2d at 960. Accordingly, “[a] genuine issue of material fact is not created where the only issue of fact is to determine which of the two conflicting versions of the plaintiff’s testimony is correct.” *Id.*

The sham affidavit rule bars Dr. Bliesner's declaration, which repeatedly contradicts both his expert report and deposition testimony. A non-exhaustive list of the contradictions includes:

- In his report, Dr. Bliesner noted a report of a digoxin lot, 60319A, where the standard deviation for final blend assay "was 4.5% which was higher than other batches." (Bliesner Report at 43). Although this 4.5% deviation falls within the FDA-approved range (*see* Pls' Exhibit 253 at 6), Dr. Bliesner now describes the same incident as: "Actavis confirm[ing] . . . blend uniformity *defects*." (Bliesner Decl. at 4) (emphasis added).
- In his report, Dr. Bliesner cites an internal UDL e-mail noting "low assay" values of 96.2 and 97.3% in batches 70926A1 and 70953A1. (Bliesner Report at 57). Although these values fell within the FDA-approved assay range (*see* Pls' Exhibit 016 at 46), Dr. Bliesner's declaration describes this incident as "confirm[ing] two batches of Digitek 0.125 mg tablets *with out-of-specification assays* (too low)." (Bliesner Decl. at 4)(emphasis added).
- In his report, Dr. Bliesner cites a reference to an investigation (number 08-030 for Lot 80133A) prompted because an "[o]perator noticed tablets that were thinner than a typical tablet during inspection of drum #2." (Bliesner Report at 59). But although the record does not indicate what this investigation concluded, Dr. Bliesner now reports that "Investigation No. 08-030 *confirm[ed]* discovery of *out-of-specification* (sub-thickness) tablets in bucket no. 2 of batch no. 80133A." (Bliesner Decl. at 4) (emphasis added).
- In his report, Dr. Bliesner quotes the recall notice—"This recall notice [sic] has been initiated due to overweight tablets." (Bliesner Report at 17). His declaration, however, alludes to a far wider range of problems: "On April 24, 2008, a Class I nationwide recall of all Digitek tablets . . . is announced, due to *double-thickness* tablets, overweight tablets, and/or *blending defects*." (Bliesner Decl. at 5) (emphasis added). None of the FDA-approved recall notices said that.
- During his deposition, Dr. Bliesner agreed that the 2008 report from a Massachusetts nursing facility, which identified an allegedly double-thick tablet, was not reliable. Nevertheless, Dr. Bliesner relies on this very report in his declaration, stating: "[J]ust days after notice of the Digitek recall, Mylan confirms that a digitek tablet of 'obviously double thickness' is reported to have been discovered by the staff of a Massachusetts nursing facility . . . . There is no indication that any effort was made by defendants to specifically preserve this *defective* tablet, which is now reportedly missing." (Bliesner Decl. at 5). Moreover, he assumes without support that the tablet was returned to Defendants and was in fact out of specification.
- In his report, Dr. Bliesner quotes a 2008 FDA report involving an inspection of Actavis's Riverside facility, stating that the "inspection was limited to coverage of the Quality System due to significant cGMP deficiencies." (Bliesner Report at 17). But in his declaration, Dr. Bliesner editorializes, without support, that FDA inspected the facility

due to “significant cGMP deficiencies” relating to “the prevention and remediation of double-thick tablets and blending failures.” (Bliesner Decl. at 4).

In summary, when Dr. Bliesner prepared his declaration, he reviewed the same evidence as when he prepared his expert report. But this time, without explanation, he added a new opinion that each of those pieces of evidence related to out-of-specification or defective Digitek®. Seen in this light, his declaration amounts to nothing more than a vehicle by which Plaintiffs attempt to close the gap between the record they have developed and their burden of proof. It does not create genuine issues of material fact.

Had Dr. Bliesner stated the same opinions in his expert report or during his deposition that he offers in his declaration, Defendants would have asked questions exploring these opinions. By offering them after the close of discovery and after the deadline for motions to exclude his testimony, Plaintiffs have deprived Defendants of any opportunity to examine Dr. Bliesner’s new opinions. For this reason, alone, his new opinions regarding defective and out-of-specification Digitek® should be barred even if this Court does not find that either Rule 26(e)(2) or the “sham affidavit” rule exclude his declaration.

### **CONCLUSION**

Plaintiffs’ burden to prove defect cannot be satisfied with circumstantial evidence that does no more than attack Actavis for a history of regulatory problems not related to out-of-specification Digitek® tablets. This Court should reject Plaintiffs’ attempt to shift the burden of proof onto Defendants and grant summary judgment on all remaining claims in MDL 1968.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on September 7, 2011, a copy of the foregoing **REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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